UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,517	12/17/2001	Dennis Keith	13764-002001	4690

26161 7590 06/29/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,517	KEITH ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-56 are pending in the instant application. Restriction is required for Claims 1-56.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: 1 invention, crystalline lipopeptide compounds.

A) Claims 1-20, drawn to crystalline and amorphous daptomycin and related analogs, classified in class 530, subclass 317, for example.

Group II: 3 inventions, pharmaceutical compositions:

A) Claims 21-25 and 27, drawn to pharmaceutical compositions of daptomycin and related analogs for *oral* administration, classified in class 514, subclass 2, for example.

B) Claims 21, 22, 24, 26, and 27, drawn to pharmaceutical compositions of daptomycin and related analogs for administration *in a micronized form*, classified in class 514, subclass 9, for example.

C) Claims 21-25, 27, and 28, drawn to pharmaceutical compositions of daptomycin and related analogs for *aerosol* administration, classified in class 530, subclass 317, for example.

Group III: 11 inventions, formulations:

A) Claims 29, 30, in part, and 31 drawn to a *pharmaceutical* formulation, classified in class 424, subclass 439, for example.

B) Claims 29, 30, in part, and 32, drawn to a *feed* composition, classified in class 426, subclass 635, for example.

C) Claims 29, 30, in part, and 33, in part, drawn to a *personal care* formulation where the personal care formulation is:

i) a washing formulation, classified in class 426, subclass 635, for example.

ii) a soap, classified in class 510, subclass 103, for example.

iii) a shampoo, classified in class 530, subclass 119, for example.

iv) an antiperspirant, classified in class 424, subclass 47, for example.

D) Claims 29, 30, in part, and 34, in part, drawn to a *veterinary* formulation, where the veterinary care formulation is:

i) a *soap*, classified in class 510, subclass 103, for example;

ii) a *shampoo*, classified in class 530, subclass 119, for example;

iii) a *pharmaceutical* composition, classified in class 514, subclass 2, for example;

E) Claims 29 and 30, in part, drawn to *a food* formulation, classified in class 426, subclass 76, for example;

F) Claims 29 and 30, in part, drawn to a *cosmetic* formulation, classified in 424, subclass 400, for example.

Group IV: 5 inventions, methods of administration:

A) Claims 35-40 and 42, drawn to a method of administering a lipopeptide as a *micronized particle*;

B) Claims 35-39, 41 and 42, drawn to a method of administration where the lipopeptide is administered as a targeted release form;

C) Claims 27 and 30, drawn to a method of *oral* administration, where the oral administration is done:

i) subcutaneously;

ii) intravenously;

iii) intramuscularly;

All classified in class 514, subclass 2, for example.

Group V: 1 invention, method of manufacturing and storing crystalline lipopeptide.

A) Claims 44-56, drawn to a method of manufacturin and storing crystalline daptomycin and related analogs, classified in class 530, subclass 344, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III and Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds and compositions of Groups I-III can be produced synthetically, or extracted from the host cell in an aqueous phase. Additionally, the claims of Groups I-III do not specifically recite that they are materially connected to the methods of Group V.

Inventions of Group I-III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case as evidenced by the claims themselves, the compounds and compositions of Groups I-III can be used to treat various diseases and/or disease states. Additionally, as evidenced by the claims themselves, the compounds may be administered via various methods, each requiring a different formulation and/or physical state. Further, one could perform the inventions of Group IV with materially different compounds, such as cefazolin.

Applicant is required to elect an Inventive Group, and further required to elect a single Invention within said Group.

If Applicant selects Inventive Group I, Applicant must select one invention: A.

If Applicant selects Inventive Group II, Applicant must select one invention: A, B, or C.

If Applicant selects Inventive Group III, Applicant must select one invention: A, B, C(i), C(ii), C(iii), C(iv), D(i), D(ii), D(iii), E, or F.

If Applicant selects Inventive Group IV, Applicant must select one invention: A, B, C(i), C(ii), or C(iii).

If Applicant selects Inventive group V, Applicant must select one invention: A.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently

found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/25/04

Anish Gupta
Patent Examiner
Art Unit 1654

Andrew D. Kosar, Ph.D.
June 17, 2004